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United States Senate

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May 9, 2022

The Honorable Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

I write today requesting information regarding the Food and Drug Administration's (FDA) actions to address the dangerous shortage of infant formula.

Arkansas mothers have contacted my office because they can't get the formula they need to feed their children. Infant formula shortages have been rising since November 2021 and one study shows the out-of-stock rate for baby formula jumped from 30 percent to 40 percent in just the last few weeks. This is a direct result of the FDA's actions. On February 17, 2022, Abbott Nutrition announced it was recalling infant formulas manufactured at an Abbott facility in Sturgis, MI, due to bacterial contamination. An FDA investigation led to this shutdown and as you know, production has yet to resume.

Millions of babies rely on formula for their nutritional needs. Major retailers are limiting the amount of infant formula customers can purchase per visit, and families are being forced to pay higher prices and fees to obtain adequate food for their child. This places an additional burden on hardworking Americans already spending more on necessities due to inflation. I hope that the FDA understands the extraordinary strain this crisis has placed on parents and children alike and is doing everything in its power to re-open the Abbot plant.

At a minimum, your agency ought to provide parents with a clear timeline of when they can expect to get formula back on shelves. Please provide my office—and all parents—the following information regarding the FDA's plan to address the infant formula shortage:

1. Please identify any additional steps that must be completed prior to resuming production at the Sturgis plant, as well as an estimated timeline of when those actions will be completed.
2. Please explain what standards the FDA is using to measure whether the Sturgis plant can safely resume production.
3. While recalls have exacerbated formula shortages, there were warning signs that additional complications could lead to enormous disruptions in the supply chain. When was the FDA first alerted to potential sanitary concerns at the Abbott manufacturing facility in Sturgis, MI? What steps did the FDA take once alerted to the sanitary concerns? What is the FDA protocol when there is a potential shortage of an essential food (i.e., infant formula)?

I look forward to receiving your response.

Sincerely,

Tom Cotton
United States Senator

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